CLAIMS

Sub B1

1. A method of removing bacterial endotoxin from a pharmaceutical process solution containing an amphiphilic pharmaceutical drug or vaccine substance which method comprises treating the solution with an ionic surfactant effective to dissociate the endotoxin from the amphiphilic pharmaceutical drug or vaccine substance in the solution, and then filtering the solution through a molecular weight cut-off filter having a pore size effective to retain the amphiphilic pharmaceutical drug or vaccine substance but allow the dissociated bacterial endotoxin to pass therethrough.

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2. A method according to claim 1 wherein the pharmaceutical drug or vaccine substance comprises a polypeptide.

Ins. A5

3. A method according to claim 1 or claim 2 wherein the amphiphilic pharmaceutical drug or vaccine substance comprises a glycoprotein.

4. A method according to any one of the preceding claims wherein the amphiphilic drug or vaccine substance is a vaccine antigen.

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5. A method according to claim 4 wherein the antigen is a viral antigen.

6. A method according to claim 5 wherein the viral antigen is not in the form of whole virus.

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7. A method according to claim 5 or claim 6 wherein the antigen is an influenza antigen.

8. A method according to any one of claims 5 to 7 wherein the

antigen is a haemagglutinin and/or neuraminidase antigen.

9. A method according to any one of the preceding claims wherein the surfactant is an anionic surfactant.

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10. A method according to claim 9 wherein the anionic surfactant has a steroidal structure.

11. A method according to claim 10 wherein the surfactant is a bile salt or an analogue thereof.

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12. A method according to claim 11 wherein the surfactant is a salt of deoxycholate, cholate, glycocholate, taurodeoxycholate or taurocholate.

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13. A method according to claim 12 wherein the surfactant is deoxycholate (DOC).

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14. A method according to any one of the preceding claims wherein the surfactant is present at a concentration which is at least as great as the critical micelle concentration of the surfactant.

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15. A method according to claim 14 wherein the surfactant is present at a concentration of from one and a half to five times its critical micelle concentration.

16. A method according to claim 15 wherein the surfactant is present at a concentration of between two and four times its critical micelle concentration.

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17. A method according to any one of the preceding claims wherein

the a molecular weight cut-off filter comprises a regenerated cellulose acetate membrane, or a polysulphone membrane.

18. A method according to any one of the preceding claims wherein, following removal of the bacterial endotoxin, the process solution is subjected to a further process step in which the surfactant is removed.

19. A method according to claim 18 wherein the further process step comprises subjecting the process solution to dialysis.